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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/600,027	09/06/2000	Kiyoshi Tanabe	2000_0973A	6651

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EXAMINER

KATCHEVES, KONSTANTINA T

ART UNIT PAPER NUMBER

1636

DATE MAILED: 05/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/600,027

Applicant(s)

TANABE ET AL.

Examiner

Konstantina Katcheves

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 August 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4,6,9,10 and 14-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4,6,9,10 and 14-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claims 4, 6, 9, 10, 14-22 are pending in the present application.

Continued Prosecution Application

The request filed on 26 February 2003 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/600027 is acceptable and a CPA has been established. An action on the CPA follows.

Response to Amendment

The rejection of claims 9, and 10 under 35 U.S.C. 112, first paragraph has been withdrawn in view of Applicant's Amendment and arguments filed 13 August 2002.

The rejections under 35 U.S.C. 112, second paragraph have been withdrawn in view of Applicant's Amendment and arguments filed 13 August 2002.

Claims 4, 6, 9, 10 and new claims 14-22 remain rejected under 35 U.S.C. 103(a) for the reasons of record set forth in the Office Action mailed 27 February 2001 and in the in the Office Action mailed 6 November 2001.

Response to Arguments

Claims 4, 6, 9, 10 and new claims 14-22 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Fijalkowska et al. and Lin et al., in view of either Imamoto et al. or Iwaki et al. and further in view of Pan et al. (1996 Antimicrobial Agents and Chemotherapy 40:2321-2326) for the reasons of record in Official Action mailed 27 February 2001 and in the in the Office

Action mailed 6 August 2002.

Applicant merely asserts the present rejection is untenable. Although, Applicant has cancelled claim 1 and replaced it with independent claim 14. Claim 14 still is drawn to a method wherein point mutations are introduced into genomic DNA by using a specific mutator gene. New claim 14 now recites that the mutation step (a) is repeated. In traverse of the instant rejection in Paper no. 9, Applicant asserted that Pan et al. did not repeat the step of introduction of mutation under a certain condition and the step of selection of mutant under a selection condition and that the subsequent mutations are carried out under the same selection condition. As discussed previously this line of reasoning was not found persuasive. Pan teaches selection of ciprofloxacin-resistant mutants of *Streptococcus pneumoniae* with mutation in genomic DNA that were generated by stepwise selection at increasing drug concentrations. Pan teaches that some mutants were isolated and selected with the same selection load, i.e. drug concentration, as the previously selected mutants (see page 2322, right column, and page 2323). This method is consistent with the steps of Applicant's claims wherein the same condition is provided for the subsequent steps in the method.

Although Applicant's claims now specifically recite the use of mutators of the mis-match repair mechanism, the claims remain rejected over Fijalkowska et al. and Lin et al., in view of either Imamoto et al. or Iwaki et al. and further in view of Pan et al. Together these references teach the invention of the instant claims.

One of ordinary skill in the art would have been motivated to isolate mutations in genomic genes as a way to study the function of such genes or to identify genes that perform certain functions. One would have been motivated to use a mutator strain defective in mismatch-

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repair, as suggested by Lin et al., and a selection load condition. Further, since Lin et al. note that mutators could mutate other genes in the cell in a way that would be undesirable for the mutagenesis, one would have been motivated to modify the method of Lin et al. to limit the number of background mutations, especially since one would not have been able to predict in advance, for every situation, which background mutations would be particularly undesirable (aside from those causing death of the cell) and how to avoid getting those mutations accidentally. One would have thus been motivated use a mutator known in the art that is defective under a certain condition, such as the *dnaQ49* taught by Iwaki et al. In this way, mutations could be introduced for a defined period of time under the certain condition, and then the cell could be removed from that certain condition so that a high frequency of mutations did not continue to form indefinitely and possibly kill the cell or complicate genetic analysis by the existence of a variety of different mutations in the cell. It also would have been obvious to isolate a mutated gene from the mutant cell to see what gene was mutated and to determine the sequence of the mutation for further analysis. With respect to new claims 18-22 the optimization of amounts and conditions are within the purview of the ordinary skilled artisan such that the present claims are obvious as discussed above. Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. See MPEP 2144.04 and see *e.g. In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Conclusion

This is a continuation of applicant's earlier Application No. 09/600027. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

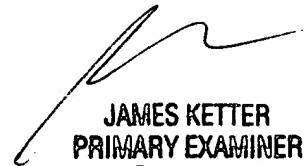
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konstantina Katcheves whose telephone number is (703) 305-1999. The examiner can normally be reached on Monday through Friday 7:30 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel, Ph.D. can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-7939 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-3388.

Konstantina Katcheves
May 2, 2003



**JAMES KETTER
PRIMARY EXAMINER**